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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,093	12/19/2001	Franz-Josef Mais	Mo6857/Lc 33,762	7790

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EXAMINER

MCKENZIE, THOMAS C

ART UNIT	PAPER NUMBER
1624	//

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,093	MAIS ET AL.	
	Examiner	Art Unit	
	Thomas McKenzie Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 September 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10,11 and 13-17 is/are rejected.
- 7) Claim(s) 12 and 18 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

1. This action is in response to arguments and a translation of the priority document filed on 9/3/03. Applicant has amended no claims. There are nine claims pending and nine under consideration. Claims 10-18 are synthesis claims. This is the second action on the merits. The application concerns the synthesis of 4,6-dichloropyrimidine from 4-chloro-6-hydroxypyrimidine. Both the starting material and the product of Applicants' process are old.

Priority

2. The translation of German Application 199 29 353.8 provides complete support for all of Applicants' pending claims. Thus, the effective filing date of all pending claims in the present application is 6/26/99. The publication date of Garner (Heterocyclic Communications) in 1999 is uncertain, however, page 508 of this reference states that the reference was received for publication on 11/8/99. The actual publication date must be after that date. Garner (Heterocyclic Communications) is no longer a competent reference against Applicants claims. The obviousness rejections made in points #5 and #6 are withdrawn.

Specification

3. The disclosure is objected to because of the following informalities: in Example 8, line 30, page 6, Applicants indicate that 6-hydroxypyrimidine has reacted. Should this not be 6-methoxypyrimidine? There is a second reference to a hydroxy compound in line 31. Appropriate correction is required.

In the previous office action, this typo was stated to occur on page 8, not on page 6. The Examiner regrets the error.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 11, and 13-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bowen (WO 95/29166 A1), or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bowen (WO 95/29166 A1). A process is inherently taught if inferences, which one would reasonably make, are taken into account, *In re Napier*, 34 USPQ2d 1782. The reference teaches the reaction of 4,6-dihydroxypyrimidine with phosgene to yield 4,6-dichloropyrimidine. What is inherent in this reference is the use of 4-chloro-6-hydroxypyrimidine as starting material. The MPEP says §2112, “[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection”. “There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.” *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA

1977). This same rationale will also apply to process claims claimed in terms of function, property, or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims."

The reaction of phosgene or thionyl chloride with a hydroxyl compound requires one molecule of reagent for each hydroxyl group. With phosgene, one molecule of CO₂ and one molecule of HCl must be produced as by-products in the synthesis of a chlorine derivative. Only one hydroxyl group of 4,6-dihydroxypyrimidine may be transformed into a chlorine atom by the phosgene reagent. The reaction taught by Bowen (WO 95/29166 A1), thus may be pictured below. Two molecules of phosgene are required in the process of Bowen (WO 95/29166 A1). Applicants' 4-chloro-6-hydroxypyrimidine starting material is a necessary intermediate in the process taught in the prior art and thus is inherently



present in the reaction mixture of Bowen (WO 95/29166 A1). Applicants' 4-chloro-6-hydroxypyrimidine starting material is generated *in situ* in the reference. Thus, claim 13, which optionally permits "a reaction mixture containing" the starting material, is inherently anticipated. Since both the starting material and

product of Bowen (WO 95/29166 A1) are symmetrical, it is a random choice as to which hydroxyl group first reacts.

The process is found in paragraph 3, page 1, paragraphs 2-8, page 2, and Examples 1-6, pages 2-4 of the reference. Claims 10 and 11 require specific acid chlorides. Phosgene is an acid chloride of formula Cl-CO-Cl. Thus claims 10 and 11 are anticipated. Claims 14 and 15 require use of one equivalent of acid chloride and specific solvents. Line 26 on page 2 of the reference teaches that 2.5 to 3.6 moles of phosgene are required for each mole of starting material. Aromatic, nitrile, ether, and polyether solvents are taught in paragraph 2 on page 2. Thus, claims 14 and 15 are anticipated. Claims 16 and 17 specify temperature and pressure. Reaction temperatures of -10 to 130°C are taught in paragraph 3, page 2 of the reference. The reference is silent as to the pressure used but since the refluxing temperature of methylene chloride is reported as 29°C in Example 2, a pressure of 1 bar may be inferred. Thus, claims 16 and 17 are anticipated.

A process claim is anticipated even if patentee of prior art did not recognize that an "inventive concept" of the new claim was necessarily present, not merely probably or possibly present, in the prior art, *Verdegaal Brothers Inc. v. Union Oil Company of California* 2 USPQ2d 1051. *Mehl/Biophile International Corp. v. Milgram* 52 USPQ2d 1303, "[i]nherency is not necessarily coterminous with the

knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art."

Applicants make four arguments and pose one question to the Examiner concerning this rejection. The question is why Bowen (WO 95/29166 A1), would choose 4,6-dihydroxypyrimidine as starting material to make 4,6-dichloropyrimidine rather than choose Applicants' 4-chloro-6-hydroxypyrimidine as starting material. 4,6-Dihydroxypyrimidine requires two displacement reactions while 4-chloro-6-hydroxypyrimidine requires only a single displacement reaction. The answerer is the commercial availability and cost of the two possible starting materials. The Examiner's 1992 copy of the Aldrich Chemical catalog reveals an entry on page 466 offering 4,6-dihydroxypyrimidine for sale at \$7/gram. There is no entry offering 4-chloro-6-hydroxypyrimidine for sale. Bowen (WO 95/29166 A1) elected to use a readily available and lower costing starting material, rather than the 4-chloro-6-hydroxypyrimidine used by Applicants, even though it resulted in a more complex process.

The four arguments made by Applicants are that Bowen (WO 95/29166 A1) used a base, which Applicants did not. Secondly, they assert that that 4-chloro-6-hydroxypyrimidine is not an intermediate in the process taught by Bowen (WO 95/29166 A1). Thirdly, they argue that no external evidence was used by the

Examiner to prove the inherency of 4-chloro-6-hydroxypyrimidine in the prior art. Fourthly, they assert that the skilled organic chemist would not have recognized the intermediacy of 4-chloro-6-hydroxypyrimidine and cite *Ex parte Viscardi* 136 USPQ 382 in support of their position. This is not persuasive and there would appear to be a conflict between Applicants' second and fourth arguments.

It is admitted that the prior art repeatedly emphasizes the importance of base and contains no examples of any reaction lacking a base. However, Applicants claims use the open term "comprising". Thus, processes with additional reagents anticipate Applicants' claims. In any event, lacking unexpected results, omitting an ingredient is an obvious modification of a chemical process, *In re Wilson* 153 USPQ 740.

To the second point, assertion is not evidence. The Examiner agrees that case law requires inherency must be certain, *In re Rijckaert* 28 USPQ2d 1955, *In re Oelrich* 212 USPQ 323, *In re Robertson*, 49 USPQ2d 1949. Applicants may prove that the prior art does not possess the inherent characteristic, *Ex parte Grey* 10 USPQ2d 1922. In the present case Applicants have offered no such proof. The fundamental laws of chemistry concerning conservation of atoms and balanced equations make certain that the reaction of phosgene with 4,6-dihydroxypyrimidine proceeds in two distinct steps. Thus, it is certain that 4-chloro-6-

hydroxypyrimidine is produced and consumed in the prior art. That is why no rejection over the PCl_3 and POCl_3 processes of Jones (GB 2,325,224 A) was made. These phosphorus reagents are capable of delivering two or more chlorine atoms to a target molecule. While it is likely that Applicants' 4-chloro-6-hydroxypyrimidine starting material is an intermediate in the reaction of 4,6-dihydroxypyrimidine with POCl_3 to yield 4,6-dichloropyrimidine as taught by Jones (GB 2,325,224 A), that possibility is not the certainty required by the case law.

Thirdly, external evidence is not required to make an inherency rejection. The Examiner may rely upon scientific reasoning, *Ex parte Levy*, 17 USPQ2d 1461. Fourthly, *Ex parte Viscardi* 136 USPQ 382 was a mechanical case involving the reduction of static electricity with CO_2 gas. The board decision rested on two factual questions, whether the CO_2 of the prior art was in a solid or liquid form initially and whether the concentration of CO_2 in the prior art was sufficient for the purpose of reducing static. There was no question in *Ex parte Viscardi* 136 USPQ 382 if CO_2 gas was present or absent in the prior art. The presence or absence of 4-chloro-6-hydroxypyrimidine in the prior art is the critical question in the present case, not its concentration or physical form.

Allowable Subject Matter

5. Objection is made to claims 12 and 18 as dependant upon a rejected claim. The following is a statement of reasons for the indication of allowable subject

matter: Applicants claims are patentable over Doyle ('199). Although Doyle ('199) pictures Applicants' claimed process at the lower left portion of Figure, this reference has an effective filing date of 7/7/00 and may not be applied against Applicants claims. The claims of Doyle ('199) are drawn to a process of making 4,6-dichloropyrimidine from acyclic imidoyl chlorides and do not form a potential interference with the claims of the present application.

Conclusion

6. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for amendments is (703) 872-9306. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, you can reach the Examiner's supervisor, Mukund Shah at (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.


Thomas C. McKenzie, Ph.D.
Patent Examiner
Art Unit 1624

TCMcK

